SDA The Soap and Detergent Association
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C T F A
THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

June 30, 2000

Charles J. Ganley, M.D.
Director
Division of OTC Drug Products (HFD-560)
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: Topical Antimicrobial Drug Products - Health-Care Antiseptic Drug Products for OTC Human Use (Docket No. 75N-183H)

Dear Dr. Ganley:

This letter is sent on behalf of members of The Soap and Detergent Association (SDA) and The Cosmetic, Toiletry, and Fragrance Association (CTFA) Industry Coalition.

During recent conversations you indicated that your staff is reviewing the OTC docket for topical antimicrobial products in order to prepare an internal recommendation on how the Agency should progress to a Final Monograph for Health-Care Antiseptic Drug Products.

As the Industry Coalition reviews the tasks which must be completed prior to adoption of a Final Monograph, there are two major issues which underpin all product categories in the Health Care Continuum Model (HCCM) as proposed by the Industry Coalition. These are 1) finalizing details of finished product test methodology and 2) evaluating Category I status for active ingredients. The Coalition respectfully requests that the Agency consider these issues for all products included within the HCCM, rather than addressing them on an individual product category basis.

1. Finalization of finished product test methodology

   The test methods described in the Industry proposal on finished product testing submitted September 29,1999, simulate the expected in-use conditions of the product intended for marketing, and are specific to body site and the target flora. However, many of the methodological issues which require resolution, such as neutralization and statistics, are common to all of the proposed methods, and the Coalition urges that the Agency deal with these as a first priority. As previously discussed, valid and reproducible test methods must be established before performance criteria for the HCCM product categories can be set.

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2. Evaluating Category I status for active ingredients

   The antimicrobial active ingredients identified in the Tentative Final Monograph can be used to formulate products in several of the HCCM product categories. Many of these active ingredients have not yet attained Category I status. Again, the Coalition requests that the Agency consider the acceptability of the active ingredients across the entire HCCM, rather than on a product by product basis.

The Industry Coalition appreciates your efforts to complete the Monograph in the most efficient manner possible and reaffirms its willingness to work with FDA to achieve this goal.

Sincerely,

Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association

Jenan Al-Atrash, Dr. PH
Director, Human Health & Safety
The Soap & Detergent Association

cc: Linda Katz, M.D. (HFD-560)
Debbie Lumpkins (HFD-560)